# In the United States Court of Federal Claims
**OFFICE OF SPECIAL MASTERS**
**No. 21-1845V**

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| TERRY W. CHRISMAN, | * | Chief Special Master Corcoran |
| Petitioner, | * | Filed: April 18, 2024 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

*Kevin A. Mack,* Law Offices of Kevin A. Mack, LLC, Tiffin, OH, for Petitioner.

*Mallori B. Openchowski*, U.S. Department of Justice, Washington, DC, for Respondent.

## ENTITLEMENT DECISION[1]

On September 13, 2021, Terry Chrisman filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petition (ECF No. 1) at 1. Petitioner alleges that an influenza ("flu") vaccine he received on November 16, 2018, caused him to incur Guillain-Barré syndrome ("GBS"). *Id.* In particular, Petitioner maintains that he can satisfy the requirements of a flu vaccine-GBS Table claim—a contention Respondent disputes.

The parties have submitted briefs regarding whether Petitioner meets the elements of a Table claim for GBS after the flu vaccine. *See* Respondent's Motion, dated Nov. 7, 2023 (ECF No. 35) ("Mot."); Petitioner's Opposition, dated Dec. 28, 2023 (ECF No. 38) ("Opp."). For the

[1] "Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id."*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

reasons stated in more detail below, I find not only that a Table claim is not viable, but also that *no* claim based on the facts of this case can succeed.

## I. Fact History

*Medical Issues Immediately Prior to Vaccination*

Petitioner's medical history includes chronic obstructive pulmonary disease ("COPD"), lower back pain, right-sided adhesive capsulitis and paresthesias, and smoking. Ex. 2.1 at 43–104; Ex. 1 at 85–87. Two weeks before the vaccination at issue, he saw his primary care provider ("PCP") on November 6, 2018, reporting a two-week history of cough, chest tightness, and sinus pressure. Ex. 1 at 35–36. He also speculated that cleaning at his workplace had caused a flare of his COPD. *Id*. at 35. He was at this time diagnosed with acute sinusitis and COPD exacerbation and prescribed medication, including an antibiotic. *Id*. at 36.

Mr. Chrisman returned to his PCP more than a week later, on November 15, 2018, reporting a low-grade fever, dizziness, and chest pain, and complaining that his medications did not seem to ameliorate his condition. Ex. 1 at 32–33. He was accordingly sent that day to Van Wert County Hospital for an X-ray. Ex. 2.1 at 372–74, 475–83. There, Petitioner was seen in the emergency department, and he appeared confused, reporting blurry vision and headache. A head CT revealed bilateral ethmoid sinusitis, but an echocardiogram ("ECG") was negative. A complete blood count revealed mildly elevated white blood cells and an elevated eosinophil count. Based on his overall presentation, Petitioner was admitted to the hospital for possible syncope. *Id*. at 483.

Thereafter, Petitioner underwent a number of additional tests (a carotid doppler, ECG, stress test, and brain MRI), but all yielded negative results. He also remained afebrile. Ultimately, Petitioner was discharged and given additional medications, including an antibiotic plus treatments for an upper respiratory infection. Ex. 2.1 at 383–390, 413, 415, 419–422, 463. At the time of discharge on November 16, 2018, he received the flu vaccine that is the subject of this claim. *Id*. at 446, 451.

*Neuropathic-Like Symptoms After Vaccination*

There is no record evidence of Petitioner having any reaction to the November 16th vaccination. But four days later, on November 20, 2018, Mr. Chrisman returned to his PCP for follow-up, complaining of additional or revived symptoms. Ex. 1 at 30–31. In particular, the dizziness he had experienced before hospitalization had returned, and he had stumbled when walking into work the day prior (or November 19th—three days post-vaccination). He also again complained of blurry vision, plus a spinning sensation, and exam revealed bilateral lower extremity weakness. However, the nurse practitioner who saw him recommended that he complete the

antibiotic course he had been prescribed at the hospital as well as a new medicine for treatment of vertigo, and he obtained a cardiologic appointment for early December. *Id.*

Petitioner again saw his PCP nine days later (November 29, 2018), complaining of continued dizziness, blurry vision, drooling, headache, numbness and tingling, plus unsteadiness and weakness in his bilateral lower extremities, and a "spacey" affect (in the view of his spouse). Ex. 1 at 26–29. He presented at this time with a mild fever (100.1 degrees), but no respiratory distress. *Id.* at 26–27.

A few days later (now early December), Petitioner was admitted to a different hospital for treatment of increasing, ascending bilateral lower extremity weakness. Ex. 3 at 19–27. His wife described the symptoms as beginning "about 2 weeks ago," which if correct would place onset in mid-November, very close-in-time to vaccination. *Id*. at 19. The record from this event reveals that treaters were informed Petitioner had been complaining of dragging his foot and numbness into the feet, and that he had received the flu vaccine for the "very first time" after his prior hospitalization, but was concerned about side effects. Exam revealed no fever, pain, incontinence, cough, or wheezing, but Petitioner did exhibit moderate bilateral weakness which was deemed "concern[ing]" for GBS. *Id*. at 21. He was thereafter admitted for further evaluation. *Id.* Around this time, Mrs. Chrisman provided treaters more details about her husband's course, noting that he had received the vaccine on November 16th, with onset of progressive ascending weakness the very next day. *Id.* at 29.

Petitioner himself also educated neurology treaters at this time about his history, noting his prior experiences with visual changes and vertigo, and adding it had begun three weeks ago, with tingling and numbness from his feet to his knees starting the next week. Ex. 3 at 29, 80. Exam revealed moderate to severe weakness in his bilateral lower extremities, with some fluctuations, decreased pain and temperature sensation below the knees, but normal reflexes in his arms and legs. *Id.* at 80.

The neurologist who first saw Petitioner at this second hospitalization opined that there was no "definite clinical evidence" of GBS based on Petitioner's intact reflexes and absence of arm paresthesias or weakness, but recommended further imaging and a lumbar puncture. Ex. 3 at 81. However, this testing proved largely unrevealing. An MRI of Petitioner's cervical spine revealed only mild diffuse disc osteophytic bulge, with right greater than left spurring resulting in mild right neural foraminal stenosis. *Id.* at 99–100. The MRI of his thoracic spine revealed no evidence of abnormal cord or enhancement, disc herniation, spinal stenosis or neuroforaminal narrowing. *Id.* at 106–07. Finally, an MRI of his lower spine revealed mild diffused disc bulges at L4-5 and L5-S1 with a disc fragment abutting the right S1 nerve root. *Id*. at 100–01. And a cerebrospinal fluid study revealed slightly elevated protein (54, with 15-45 normal), but no

evidence of infectious pathology. *Id*. at 110–16. Based on all the foregoing, the attending physician could provide no explanation for petitioner's weakness. *Id*. at 51.

By December 7, 2018, Petitioner was reporting some improvement in his lower extremity weakness, although he was experiencing a painful frontal headache and neck stiffness. Ex. 3 at 56–58. It was thereafter noted by the attending internal medicine physician that Petitioner's work-up was not consistent with a neurologic explanation for his symptoms, but that those same symptoms were nevertheless "consistent" with GBS (which had been reported to occur "after swine flu immunization"). It was accordingly recommended that Petitioner obtain an EMG study and be tested for certain antiganglioside antibodies associated with GBS. *Id*. at 63. His lower extremity symptoms and headache thereafter improved enough that he was permitted to be discharged to a rehabilitation facility, with the diagnoses of improving "symmetric ascending weakness and paresthesia," resolved headache, improving vertigo, ethmoid sinusitis, vitamin D deficiency, and COPD. *Id*. at 67, 74, and 89–91.

Mr. Chrisman remained in a rehabilitation in-patient from December 11-20, 2018. Ex. 5 at 52–56. Records from this treatment period reveal he reported onset of "funny feelings" in his legs within 48 hours of receiving the flu vaccine. *Id*. at 52. His condition was described as bilateral lower extremity paresis "of unclear etiology but improving," and it was noted he had received recent administration of a flu vaccine during an "upper respiratory illness with fever." *Id*. at 55. At discharge Petitioner was deemed to have achieved his rehabilitation goals, and to display improving bilateral lower extremity paresis of unclear etiology, but sufficient gait/postural instability that he needed a rolling walker to ambulate. *Id.* at 57–58, 401–02. Toward the end of that December, Petitioner obtained an initial physical therapy ("PT") evaluation, and although he again complained of some symptoms comparable to what he had previously experienced (*i.e.,* leg discomfort, random numbness/tingling, decreased strength, and difficulty with walking) it was also noted that no "true 'diagnosis'" had yet been proposed as explanatory (although he continued to express the personal view that the flu vaccine was responsible). *Id*. at 334–36, 346.

*Treatment in 2019 and Thereafter*

Petitioner has filed records reflecting additional treatment he received from January 2019 to the summer of 2023. But, although he can substantiate evidence of ongoing medical concerns somewhat consistent with what he experienced in 2018 (pre- and post-vaccination), his subsequent history sheds limited light on the fundamental question of vaccine causation—or the precise diagnostic nature of his alleged injury.

For example, Petitioner underwent the previously-recommended EMG in January 2019, but it yielded normal results, not consistent with a neuropathy. Ex. 2.1 at 361; Ex. 4 at 190. ("[t]his is a normal upper and lower extremity nerve conduction study/EMG."). He had a follow-up visit

with his PCP in May 2019, and although he continued to report some neuropathic-like symptoms (*e.g.*, fatigue, weight gain, lower extremity weakness, and ambulation difficulties), no neurologic explanation was identified or proposed. Ex. 1 at 16–21. Indeed, an EEG performed on May 31, 2019, to evaluate unusual eye movements and left-hand jerking produced more normal results, and hand twitching he reported was deemed associated with episodes of hyperventilation that were "nonepileptic in nature." Ex. 3 at 15–16.

During the summer of 2019, Mr. Chrisman attended additional PT sessions (Ex. 2.1 at 945–48), and displayed improved strength but unchanged gait mechanics by September. Ex. 2 at 762–763, 945–48. He also that summer began to obtain anxiety therapy, with some treaters proposing that certain symptoms, like a neck twitch, were likely stress-induced. Ex. 1.2 at 29–34.

In 2020, Petitioner continued to have respiratory and breathing issues (some of which were deemed attributable to his smoking again), plus neck spasms and gait abnormalities, plus ongoing lower extremity weakness (and he reported onset of his symptoms a day after vaccination). Ex. 1 at 7–9, Ex. 4.2 at 51–52. At a neurologic exam in January 2020, Petitioner displayed trace reflexes and patchy decreased sensation in his left lower extremity, and a motor exam of the left upper extremity was interrupted by spasms with "questionable give way or effort dependent qualities." *Id*. at 52. His treater proposed "an emotional component" for his symptoms, and also recommended Botox treatments for neurologic pain. *Id*.

By early fall 2020, Petitioner was reported to be experiencing unresponsive "spells," along with twitching and seemingly-allergic symptoms. Ex. 4.2 at 18. At a primary care evaluation in September 2020, he was noted to not be consistent with certain vitamin supplements he had previously been prescribed, but also that the Botox treatments were ineffective, and he was smoking and drinking heavily. Ex. 1.2 at 5–10. Petitioner's PCP recommended that he return to his neurologist, and also to consult cardiology to ensure the episodes were not cardiac-related. *Id*. at 7. He had additional such episodes that same month, plus increasing upper-extremity pain, and eventually re-entered PT. Ex. 4.2 at 9, Ex. 2.2 at 302–07. The record reveals several other instances of additional treatment events due to comparable symptoms in 2021 and 2023, but although some histories alluded to prior GBS (something not clearly set forth in the prior records), none of the records from these instances corroborate vaccine causation, or reflect treater conclusions that would be consistent with sequelae left from his purported GBS in 2018. *See, e.g.*, Ex. 6 at 7–10; Ex. 11 at 2–4.

## II. Treater Report

Although the tempo of Petitioner's treatment course slowed considerably over the three years from the date of vaccination to the filing of this claim, Petitioner did visit a treater—certified physician's assistant Jordan N. Bulcher—in 2023 (well after the claim's initiation, it should be noted), and PA-C Bulcher has offered some statements in support of the claim. *See* January 31,

2023 visit and accompanying letter, dated Mar. 2, 2023, filed as Ex. 9 (ECF Nos. 25 and 27); Letter, dated July 14, 2023, filed as Ex. 10 (ECF No. 33) ("Bulcher Ltr."). Petitioner has not filed any documentation setting forth PA-C Bulcher's credentials or qualifications.

The first record of Petitioner's January 2023 visit with PA-C Bulcher was limited. It notes Petitioner's vitals at the time, and indicates he was seen to address "[GBS] after administration of vaccine." Ex. 9 at 2. It also lists his then-current medications, which included gabapentin (used in the treatment of neuropathic pain). *Id.* at 3. The second part of the relevant record, however, included a letter from PA-C Bulcher providing more details of his visit with Petitioner. *See* Ex. 9 at 11. This letter includes PA-C Bulcher's summary of Petitioner's medical history, deeming his December 2018 presentation to be "typical of [GBS]." *Id.* It also notes that at the time of Petitioner's 2023 consultation, he still appeared to lack lower right extremity sensation and strength, as well as "an absence of small and large fiber sensation," all of which caused Petitioner to need a leg brace for walking and standing. *Id.* at 9, 15–16, 24–25. PA-C Bulcher concluded Petitioner had likely experienced flu vaccine-associated GBS, although he noted that his evaluation was performed without a supervising physician's input. *Id.* at 25.

PA-C Bulcher's second letter proposes that the medical record reveals an onset of November 19, 2018, based on reports to treaters by Petitioner or others, such as his wife. Bulcher Ltr. at 2. He also disclaims any pre-existing condition as explanatory of Petitioner's injury. *Id.* This letter is otherwise conclusory, however, and provides no explanation (beyond what PA-C Bulcher gleaned from his own reading of the medical records) for Petitioner's alleged GBS.

## III. Procedural History

The claim was initiated in September 2021, and activated in March 2022 after completion of "pre-assignment review" (performed in all Vaccine Program cases to ensure sufficient records have been filed for case review). That September, Respondent noted that it was unclear from the record what was the nature of Petitioner's injury, and therefore requested clarification. ECF No. 22. In reaction, Petitioner filed additional medical records purporting GBS to be the injury—but Respondent's subsequent Rule 4(c) Report maintained that the Table elements for such an injury could not be met under the facts of this case. *See* Rule 4(c) Report, dated Apr. 14, 2023 (ECF No. 29). Petitioner then filed the letter opinion of Mr. Bulcher, and in turn Respondent proposed that dismissal of the alleged Table claim (at a minimum) was appropriate. The matter is now briefed and ready for determination.

## IV. Parties' Arguments

*Respondent*

Respondent not only challenges Petitioner's ability to meet the Table requirements for a flu vaccine-GBS claim, but also contends that a causation-in-fact claim cannot succeed given the record. Mot. at 13. Regarding the Table claim specifically, Respondent argues that Petitioner's onset began *less than* three days post-vaccination, and hence is inconsistent with the Table timeframe of 3-42 days for onset. *Id.* at 15. Although Respondent admits that many records are vague in terms of onset, he stresses that later on (during the December hospitalization in particular) treaters were informed that Petitioner's weakness began November 17th or 18th. *See, e.g.*, Ex. 3 at 29 (November 17th as onset); Ex. 5 at 52 (November 18th); Ex. 2.1 at 334 (November 18th); Ex. 4.2 at 51 (onset within 24 hours of vaccination). Only in connection with the filing of the Petition was a later onset alleged. Mot. at 16.

More broadly, Respondent argues that the injury of GBS itself is not corroborated by the record. Mot. at 13–15. He notes that "providers struggled" to identify a diagnosis or etiology explanatory of Petitioner's symptoms, and that his "intact reflexes and absence of arm paresthesias or weakness" were inconsistent with GBS's clinical features, as defined by the Table. *Id.* at 13–14. The same was true of Mr. Chrisman's EMG/NCS results, which were deemed normal. *Id.* at 14. At most, some treaters *considered* GBS as a possible diagnosis, but did not later embrace it as explanatory, as reflected in discharge comments. *Id.* And other diagnoses, like myelitis or myositis, could also be found in the record. *Id*. At bottom, Petitioner's overall lingering course was inconsistent with GBS's monophasic character, there was no instance in which a contemporaneous treater clearly embraced the diagnosis, and Petitioner experienced many symptoms not consistent with GBS, like neck spasms. *Id.*

*Petitioner*

Mr. Chrisman maintains he has met the elements of a flu vaccine-GBS Table claim. He notes that at the time of his November 20th PCP visit, he had experienced lower extremity weakness the day before (which would be three days post-vaccination, and hence consistent with the Table claim timeframe)—although as support for this contention, he references an affidavit signed by Mrs. Chrisman several years after the fact. Opp. at 1; Affidavit, dated Nov. 25, 2023, filed as Ex. 12 (ECF No. 37-1). He also stresses the neurologic-like nature of these symptoms, which progressed into early December, resulting in his second hospitalization. Opp. at 1–2. And treaters who first saw him at this time expressed concern that he was experiencing some GBS-like demyelinating injury. *See, e.g.*, Ex. 3 at 21. The progression of these symptoms over a two-week period meant they likely began three days post-vaccination. Opp. at 3. And nothing else in the

record supports an earlier onset. *Id.* Petitioner's opposition makes no mention of any of the other grounds Respondent raises for dismissal, however.

## V. Applicable Legal Standards

### A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[3] In this case, Petitioner asserts a flu-vaccine/GBS Table claim.

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 , 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

[3] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'")

(quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability,

injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or

inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir.

2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

## ANALYSIS

### Petitioner Has Not Established a Cognizable Vaccine Injury

There is some question as to whether under the facts of this case the Table onset for a flu-GBS claim can be met, since many of the filed medical records suggest Petitioner's neurologic symptoms began *outside* the Table's 3-42 day timeframe, within a day or two of vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). For example, four days following receipt of the flu vaccine, on November 20, 2018, Petitioner had apparently already reported a history of bilateral leg weakness and an instance where he stumbled while walking. Ex. 1 at 30. During Petitioner's second hospitalization, on December 4, 2018, Petitioner's wife more specifically reported that Petitioner's weakness began on November 17, 2018, one day post-vaccination. Ex. 3 at 29. Medical records thereafter continue to document Petitioner's onset of symptoms within one to two days of vaccination. *See* Ex. 5 at 52 (documenting weakness beginning within 48 hours of receiving flu vaccine); Ex. 2.1 at 334 (reporting pain from flu shot he two days prior to onset of symptoms); Ex. 4.2 at 51 (describing a tingling sensation in Petitioner's hands and feet within 24 hours following receipt of his flu vaccine). By contrast, one of the earliest post-vaccination records—from November 20, 2018—*does* support Petitioner's contention that he experienced some ambulatory issues, arguably attributable to leg weakness, the day before, or the 19th, meaning three days post-vaccination. Ex. 1 at 30–31.

But the claim falters on a more foundational matter—for I cannot conclude on the basis of this record that it has been preponderantly shown that Petitioner experienced GBS *at all*. 42 C.F.R. § 100.3(c)(15). Because GBS is the alleged injury, the claim is properly dismissed on this basis alone. *Broekelschen,* 618 F.3d at 1346; *see also Lasnetski v. Sec'y of Health & Hum. Servs.,* 696 F. App'x 497, 506 (Fed. Cir. 2017) (no need to perform any *Althen* analysis if alleged injury is not substantiated by evidence).

The overall record casts considerable doubt on GBS as the proper diagnosis for Petitioner's symptoms. For example, in early December 2018, Petitioner displayed intact reflexes and no upper limb parasthesias or weakness, leading one initial treater to doubt that the clinical presentation was consistent with GBS. Ex. 3 at 81. Later, the EMG/NCS testing performed in January 2019 yielded normal results (thus at least not confirming the diagnosis). Ex. 4 at 190. And while no treaters ever

fully accepted GBS as etiologically explanatory, they also considered myositis[4] or myelitis[5] as competing diagnoses. His treatment and testing from the start of 2019 to the present are not confirmatory of the proposed GBS diagnosis. And I give little weight to PA-C Bulcher's embrace of a GBS diagnosis; not only was it generated more than four years after vaccination (and obtained from a medical professional whose opinion should be deemed somewhat less reliable than a credentialed neurologist), but it was generated in response to litigation demands, and thus does not reflect a contemporaneous treater view.

In many cases, the inability to establish some Table elements would not be grounds for dismissal. Indeed, if the medical evidence more clearly supported a GBS diagnosis/injury, Respondent's onset objections would not mean the end of the claim. Alternatively, some other kind of demyelinating injury that does not quite meet the diagnostic criteria for GBS can succeed in some cases.

Here, however, the evidence of GBS is preponderantly lacking (even if it was reasonably *considered* as potentially explanatory by treaters at one point).[6] And the record does not support the conclusion that Petitioner experienced some other kind of neurologic injury (and Petitioner has not proposed what that would be). It can actually be deemed from this record that Petitioner's presentation post-vaccination related to his pre-vaccination conditions. And there is no evidence of any suspicious vaccine reaction that could suggest an aberrant immune response had begun. No testing or clinical observations make causation by vaccine likely, and no treaters (beyond PA-C Bulcher) have offered the opinion that the flu vaccine was causal of Petitioner's symptoms.

Accordingly, a causation-in-fact claim could not succeed on this record. In fact, I cannot conclude that *any* cognizable injury occurred that might have more than a coincidentally-temporal relationship to vaccination, such that the claim should be adjudicated as a non-Table matter. Thus (and relying on my expertise as a special master, in identifying what claims should or should not

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[4] "Myositis" is defined as "inflammation of a voluntary muscle; called also inflammatory myopathy." *Myositis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32923&searchterm=myositis (last visited Apr. 18, 2024).

[5] "Myelitis" is defined as "1. Inflammation of the spinal cord, often part of a more specifically defined disease process. One group of diseases is named according to whether primarily white matter or gray matter is affected (see leukomyelitis and poliomyelitis); another group is defined by whether there is coexistent disease of the meninges (meningomyelitis) or the brain (encephalomyelitis). In practice, the term is also used to denote noninflammatory lesions of the spinal cord; see myelopathy. 2. Inflammation of the bone marrow; see osteomyelitis." *Myelitis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32680&searchterm=myelitis (last visited Apr. 18, 2024).

[6] Because of such evidence, the claim's reasonable basis is not in doubt. GBS was at least included in treater differential diagnostic considerations, and *some* of Petitioner's symptoms, as set forth in the record, resemble it. Establishing reasonable basis for asserting a claim is not, however, equivalent to offering preponderant proof in its support.

proceed given the medical evidence), it is proper to dismiss this case entirely. Petitioner's overall disease course is not likely reflective of a vaccine-caused injury.

**CONCLUSION**

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[7]

**IT IS SO ORDERED.**

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[7] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.